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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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Jeffrey S. Steen, Esq.
Dilworth & Barrese, LLP
333 Earle Ovington Blvd.
Uniondale, NY 11553

EXAMINER

COLE, MONIQUE T

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/766,522

Applicant(s)

OBAYAN ET AL.

Examiner

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2001 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-27 is/are allowed.
- 6) ☒ Claim(s) 1-19 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

The Examiner has withdrawn the prior restriction requirement after further consideration. An action on claims 1-34 now follows.

Claim Objections

1. Claim 33 is objected to because of the following informalities: it depends from a nonexistent claim 50. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 & 28-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a correlation step between the detected color reaction product and its relationship to the determination of oxidative stress and/or the identification of a mammalian subject in need of medical treatment.
3. Claims 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 16 recites the presence of a minimal method used in conjunction with the claimed method. It is unclear what kind of minimal method Applicant contemplates. Further clarification is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 11, 12, 13, 15-19, 28, 32 & 34 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,702,955 to Puglia (herein referred to as "Puglia").

Puglia teaches a method for the detection of hydrogen peroxide in biological fluids such as blood, serum and urine that is useful in the diagnosis of various abnormalities. See abstract & col. 1, lines 15-17. The claimed method comprises adding to the biological a ferrous sulphate (Table 6); incubating the biological fluid and reaction reagent in the ambient air (37°C); and analyzing the color transition to detect the presence or concentration of hydrogen peroxide (claim 1). The ferrous reagent may be introduced to the solution by means of a test strip to which they have been applied (col. 2, lines 35-39). Glucose activity may be measured by reacting glucose in the presence of glucose oxidase enzyme to produce hydrogen peroxide. The hydrogen peroxide then reacts with peroxidase to catalyze the oxidation of the indicator to produce a colorimetric response directly proportional to the hydrogen peroxide concentration (col. 3, lines 39-45). Inherent to the quantification of the hydrogen peroxide concentration is some type of colorimetric standard so that one would be able to match particular colors to a particular concentration of hydrogen peroxide.

While the reference does not expressly refer to hydrogen peroxide as an indicator of oxidative stress, this determination is inherent to the claimed patent as increased physiological presence of hydrogen peroxide is a known cause of oxidative stress. See also instant specification page 1, lines 10-17 & page 4, lines 18-20.

3. Claims 1, 11, 13, 14, 16-19, 28, 29 & 34 are rejected under 35 U.S.C. 102(b) as being anticipated by "Measurement of Plasma Hydroperoxide Concentrations by the Ferrous Oxidation-Xylenol Orange Assay in Conjunction with Triphenylphosphine" by Nourooz-Zadeh et al. (herein referred to as "Nourooz-Zadeh").

Nourooz-Zadeh teaches a method of measuring hydroperoxides in plasma that comprises adding FOX2 reagent (ferrous reaction reagent) to plasma; incubating at room temperature for 30 minutes; and then measuring the absorbance of the sample. Spectrophotometers that measure absorbance always include an instruction manual. The color development in the FOX assay was due to the presence of hydroperoxides. See pages 403-405. Inherent to the quantification of the hydrogen peroxide concentration is some type standard so that one would be able to match particular colors to a particular concentration of hydrogen peroxide.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pugia.

Pugia teaches the invention substantially as claimed with the exception of teaching that the method further includes instructions. However, it is well known and appreciated in the test strip kits come with instructions informing the user of the best way to ensure accurate & reliable results, as exemplified by USP 4,904,605 (col. 2, line 68-col. 3, line 4). Thus, it would have been obvious to one having ordinary skill in the art to include instructions to the method and test kit of Pugia.

Allowable Subject Matter

7. Claims 20-27 are allowed.

8. Claims 2-10, 30 & 31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a method of colorimetrically detecting oxidative stress in a mammal using a reaction reagent comprising 2-deoxyglucose, TBA, EDTA and ferrous sulfate.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole
Examiner
Art Unit 1743

MC *MC*
May 16, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700